

REMARKS/ARGUMENTS

Status of Claims

Claims 1 and 14 have been amended.

Claims 34-52 were previously canceled.

Claims 15-17 are currently canceled.

Claims 9-10 have been withdrawn.

Claim 54 is new.

Thus, claims 1-14, 18-33, and 53-54 are currently pending in this application.

Applicants hereby request further examination and reconsideration of the presently claimed application.

Election/Restrictions

Applicants note with appreciation the Office Action's decision to take up for consideration previously withdrawn claims 4-8.

Claim Rejections – 35 U.S.C. § 103

Claims 1-8, 11-22, 25-32, and 53 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Katdare, et al., WO 95/29679 (hereinafter *Katdare*) in view of Adamski, et al., WO 01/85176 (hereinafter "*Adamski*"). Claims 1-8, 11-33, and 53 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Katdare* and *Adamski* as applied to claims 1-8, 11-22, 25-32 and 53 and in further view of Flash-Ner-Barak, et al., WO 2002/00204 (hereinafter *Flash-Ner-Barak*). Claims 15-17 have been canceled. Claims 2-8, 12-13, 18-33 and 53 depend from claim 1. Thus, the pending claims stand or fall on the application of the cited references to independent claims 1 and 14.

The Legal Standard of Obviousness Under 35 U.S.C. § 103(a)

The MPEP provides:

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.

See MPEP § 2143.

In *KSR Int'l Co. v. Teleflex, Inc.*, the United States Supreme Court also noted that, “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art,” but, additionally whether “the claim extends to what is obvious.” See *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741-42 (2007). The Supreme Court went on to explain that an obviousness determination is based upon a “proper application of *Graham*,” including consideration of “secondary factors” that may weigh against an obviousness determination. See *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. at 1745 (citing *Graham v. John Deere Co. of Kansas City, et al.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966)). The “proper application of *Graham*” begins with a determination of whether the cited prior art contains all the elements of the contested claims. See *Graham v. John Deere Co. of Kansas City*, 383 U.S. at 22 (an obviousness determination begins with a finding that “the prior art as a whole in one form or another contains all” the elements of the claimed invention). Applicants submit the pending claims are patentable over the cited references because the cited references either singly or in combination fail to contain all the elements of the instantly claimed subject matter.

Applicants have amended claim 1 to include the limitations of now canceled claim 17 and recite:

An oral formulation which includes an intragranular phase comprising a bisphosphonic acid derivative and at least one carbohydrate alcohol, together with an aqueous binder, **wherein the amount of the carbohydrate alcohol is from 15 to 40 wt.% of the weight of the formulation.**

See *supra*, emphasis added. Claim 14 has been similarly amended. The Office Action concedes the primary reference *Katdare* fails to disclose the presence of a carbohydrate alcohol and relies on *Adamski* to remedy these omissions. However, *Adamski* discloses the use of from 50 to 80 wt.% mannitol which lies outside the Applicants' instantly claimed range. See *Adamski*, page 6, lines 22 and 23. Applicants submit that absent disclosure of the instantly claimed limitation *wherein the amount of the carbohydrate alcohol is from 15 to 40 wt.% of the weight of the formulation* by either the combination of *Katdare* and *Adamski* or *Katdare*, *Adamski* and *Flash Ner-Barak* there exists an evidentiary gap that is fatal to a *prima facie* case of obviousness. Applicants respectfully request withdrawal of the rejections and allowance of the pending claims.

New Claims

New claim 54 recites novel and nonobvious aspects of the Applicants instantly claimed subject matter. Support for claim 54 can be found at least in part in paragraphs [0020] and [0031] of the instant application. Applicants fail to find disclosure of the instantly claimed *intragranular phase comprising a bisphosphonic acid derivative and at least one carbohydrate alcohol, together with an aqueous binder, wherein the amount of the carbohydrate alcohol is from 15 to 40 wt.% of the weight of the formulation* further comprising a *diluent in addition to the carbohydrate alcohol*. Also, as claim 54 depends from claim 1, claim 54 is likewise allowable over the cited references for the reasons set forth previously herein.

CONCLUSION

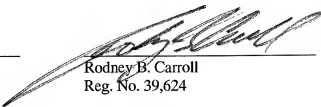
Consideration of the foregoing amendments and remarks, reconsideration of the application, and withdrawal of the rejections are respectfully requested by Applicants. No new matter is introduced by way of the amendment. It is believed that each ground of rejection raised in the Office Action dated September 16, 2010 has been fully addressed. If any fee is due as a result of the filing of this paper, please appropriately charge such fee to Deposit Account Number 50-1515 of Conley Rose, P.C., Texas. If a petition for extension of time is necessary in order for this paper to be deemed timely filed, please consider this a petition therefore.

If a telephone conference would facilitate the resolution of any issue or expedite the prosecution of the application, the Examiner is invited to telephone the undersigned at the telephone number given below.

Respectfully submitted,
CONLEY ROSE, P.C.

Date: _____

2-15-11



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